of the information would be unfair in the circumstances. Among the factors the Commission will consider in evaluating the fairness of releasing the information are the nature of the information, the fact that it is an adjunct to a Congressional protected report, and whether the information in question supports the conclusion that a section 37 or 15(b), CPSA, report should have been filed earlier.

(c) Section 6(e) imposes no confidentiality requirements on information obtained by the Commission independently of a report pursuant to section 37. The provisions of section 6(b) govern the disclosure of such information.

§ 1116.10 Restrictions on use of reports.

No member of the Commission, no officer or employee of the Commission, and no officer or employee of the Department of Justice may use information provided to the Commission under section 37 for any purpose other than to carry out the responsibilities of the Commission.

§ 1116.11 Reports of civil actions under section 37 not admissions.

Pursuant to section 37(d), 15 U.S.C. 2084(d), the reporting of a civil action under section 37 shall not constitute an admission of—

(a) An unreasonable risk of injury;

(b) A defect in the consumer product which was the subject of the civil action;

(c) A substantial product hazard;

(d) An imminent hazard; or

(e) Any other liability under any statute or any common law.

§ 1116.12 Commission response to section 37 reports.

Upon receipt of a section 37 report, the Commission will evaluate the information contained in the report and any relevant information contained in its files or data bases to determine what, if any, follow-up or remedial action by the Commission is appropriate. If the Commission requires additional information, it will notify the manufacturer in writing of the specific information to provide. In addition, the Commission will routinely review section 37 reports to determine whether the reporting manufacturers have fulfilled their obligations under both sections 37 and 15(b) in a timely manner. Such a review may also engender a request for additional information, including the dates on which final orders were entered in each of the lawsuits reported under section 37. The Commission will treat any subsequent submission of information by the manufacturer as a submission under section 37(c)(2)(B) subject to the restrictions on public disclosure contained in sections 6(a) and (b) of the Consumer Product Safety Act.

PART 1117—REPORTING OF CHOKING INCIDENTS INVOLVING MARBLES, SMALL BALLS, LATEX BALLOONS AND OTHER SMALL PARTS

Sec.

1117.1 Purpose.
1117.2 Definitions.
1117.3 Reportable information.
1117.4 Time for filing a report.
1117.5 Information that must be reported and to whom.
1117.6 Relation to section 15(b) of the CPSA.
1117.7 Confidentiality of reports.
1117.8 Effect of reports on liability.
1117.9 Prohibited acts and sanctions.

AUTHORITY: Section 102 of the Child Safety Protection Act (Pub. L. No. 103–267), section 16(b), 15 U.S.C. 2065(b) and 5 U.S.C. 553.

SOURCE: 60 FR 10493, Feb. 27, 1995, unless otherwise noted.

§ 1117.1 Purpose.

The purpose of this part is to set forth the Commission's interpretative regulations for reporting of choking incidents required by the Child Safety Protection Act. The statute requires that each manufacturer, distributor, retailer, and importer of a marble, small ball, or latex balloon, or a toy or a game that contains a marble, small ball, latex balloon, or other small part, shall report to the Commission any information obtained by such manufacturer, distributor, retailer, or importer which reasonably supports the conclusion that an incident occurred in which a child (regardless of age) choked on such a marble, small ball, or latex balloon or on a marble, small ball, latex

balloon, or other small part contained in such toy or game and, as a result of that incident the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional.

§ 1117.2 Definitions.

(a) *Small part* means any part, component, or piece of a toy or game, which, when tested in accordance with the procedures in 16 CFR 1501.4(a) and 1501.4(b)(1), fits entirely within the cylinder shown in Figure 1 appended to 16 CFR 1501.

(b) *Small ball* means any ball that under the influence of its own weight, passes, in any orientation, entirely through a circular hole with a diameter of 1.75 inches (4.445 cm) in a rigid template .25 inches (6 mm.) thick. For purposes of this designation, the term ''ball'' includes any spherical, ovoid, or ellipsoidal object that is designed or intended to be thrown, hit, kicked, rolled, or bounced, and is either not permanently attached to another toy or article, or is attached to such a toy or article by means of a string, elastic cord, or similar tether. The term *ball* includes any multi-sided object formed by connecting planes into a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball, and any novelty item of a generally spherical, ovoid, or ellipsoidal shape that is designated or intended to be used as a ball.

(c) *Choked* means suffered an obstruction of the airways.

(d) A *latex balloon* is a toy or decorative item consisting of a latex bag that is designed to be inflated by air or gas. The term does not include inflatable children's toys that are used in aquatic activities, such as rafts, water wings, life rings, etc.

(e) A *marble* is a ball made of a hard material, such as glass, agate, marble or plastic, that is used in various children's games, generally as a playing piece or marker.

(f) *Serious injury* includes not only the concept of ''grievous bodily injury'' defined in the Commission's rule for Substantial Hazard Reports at 16 CFR 1115.12(d), but also any other significant injury. Injuries necessitating hospitalization which require actual medical or surgical treatment and injuries necessitating absence from school or work of more than one day are examples of situations in which the Commission shall presume that such a serious injury has occurred.

(g) *Subject firm* means any manufacturer, distributor, retailer or importer of marbles, small balls, latex balloons, or a toy or game that contains a marble, small ball, latex balloon, or other small part.

(h) *Toy or game* includes any toy or game, including those exempt under 16 CFR 1501.3 from the small parts banning provisions of 16 CFR 1500.18(a)(9).

[60 FR 10493, Feb. 27, 1995, as amended at 60 FR 41801, Aug. 14, 1995]

§ 1117.3 Reportable information.

A subject firm shall report any information it obtains which reasonably supports the conclusion that a reportable incident occurred. Generally, firms should report any information provided to the company, orally or in writing, which states that a child choked on a marble, small ball, latex balloon, or on a marble, small ball, latex balloon or other small part contained in a toy or game *and*, as a result of that incident the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional. Subject firms must not wait until they have investigated the incident or conclusively resolved whether the information is accurate or whether their product was involved in the incident. Firms shall not wait to determine conclusively the cause of the death, injury, cessation of breathing or necessity for treatment. An allegation that such a result followed the choking incident is sufficient to require a report.

§ 1117.4 Time for filing a report.

(a) A subject firm must report within 24 hours of obtaining information which reasonably supports the conclusion that an incident occurred in which a child (regardless of age) choked on a marble, small ball, or latex balloon or on a marble, small ball, latex balloon, or other small part contained in a toy or game and, as a result of that incident the child died, suffered serious injury, ceased breathing for any length of

time, or was treated by a medical professional. Section 1117.5 of this part sets forth the information that must be reported.

(b) The Commission will deem a subject firm to have obtained reportable information when the information has been received by an official or employee who may reasonably be expected to be capable of appreciating the significance of the information. Under ordinary circumstances, 5 days shall be the maximum reasonable time for information to reach such an employee, the Chief Executive Officer or the official or employee responsible for complying with the reporting requirements of section 102 of the Child Safety Protection Act.

§ 1117.5 Information that must be reported and to whom.

(a) Reports shall be directed to the Division of Corrective Actions, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20815 (Mailing Address: Washington, D.C. 20207) (Phone: 301–504–0608, facsimile: 301–504–0359).

(b) Subject firms must report as much of the following information as is known when the report is made:

(1) The name, address, and title of the person submitting the report to the Commission,

(2) The name and address of the subject firm,

(3) The name and address of the child who choked and the person(s) who notified the subject firm of the choking incident,

(4) Identification of the product involved including the date(s) of distribution, model or style number, a description of the product (including any labeling and warnings), a description of the marble, small ball, latex balloon or other small part involved, and pictures or sample if available,

(5) A description of the choking incident and any injuries that resulted or medical treatment that was necessary,

(6) Copies of any information obtained about the choking incident,

(7) Any information about changes made to the product or its labeling or warnings with the intention of avoiding such choking incidents, including, but not limited to, the date(s) of the change and its implementation, and a description of the change. Copies of any engineering drawings or product and label samples that depict the change(s).

(8) The details of any public notice or other corrective action planned by the firm,

(9) Such other information as appropriate.

(c) Retailers or distributors should supply as much of the information required in paragraph (b) of this section as is available to them but are not required to obtain information about product design changes or recall activities from the product manufacturer.

(d) Within ten days of their initial report, subject firms must supplement their reports to supply any of the information required by paragraph (b) of this section that was not available at the time of the initial report.

§ 1117.6 Relation to section 15(b) of the CPSA.

Section 15(b) of the CPSA requires subject firms to report when they obtain information which reasonably supports the conclusion that products they distributed in commerce fail to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under section 9 of the CPSA, contain a defect which could create a substantial product hazard, or create an unreasonable risk of serious injury or death. The Commission's rules interpreting this provision are set forth at 16 CFR part 1115. The requirements of section 102 of the CSPA and this part are in addition to, but not to the exclusion of, the requirements in section 15(b) and part 1115. To comply with section 15(b), subject firms must continue to evaluate safety information they obtain about their products. Subject firms may have an obligation to report under section 15(b) of the CPSA whether or not they obtain information about choking incidents. Firms must also comply with the lawsuit-reporting provisions of section 37 of the CPSA, interpreted at 16 CFR part 1116.

§ 1117.7 Confidentiality of reports.

The confidentiality provisions of section 6 of the CPSA, 15 U.S.C. 2055, apply to reports submitted under this part. The Commission shall afford information submitted under this part the protection afforded to information submitted under section 15(b), in accordance with section 6(b)(5) of the CPSA and subpart G of part 1101 of title 16 of the CFR.

§ 1117.8 Effect of reports on liability.

A report by a manufacturer, distributor, retailer, or importer under this part shall not be interpreted, for any purpose, as an admission of liability or of the truth of the information contained in the report.

§ 1117.9 Prohibited acts and sanctions.

(a) Whoever knowingly and willfully falsifies or conceals a material fact in a report submitted under this part is subject to criminal penalties under 18 U.S.C. 1001.

(b) A failure to report to the Commission in a timely fashion as required by this part is a prohibited act under section 19(a)(3) of the CPSA, 15 U.S.C. 2068(a)(3).

(c) A subject firm that knowingly fails to report is subject to civil penalties under section 20 of the CPSA, 15 U.S.C. 2069. *Knowing* means the having of actual knowledge or the presumed having of knowledge deemed to be possessed by a reasonable person who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. Section 20(d) of the CPSA, 15 U.S.C. 2069(d).

(d) Any person who knowingly and willfully violates section 19 of this Act after having received notice of noncompliance from the Commission may be subject to criminal penalties under section 21 of the CPSA, 15 U.S.C. 2070.

PART 1118—INVESTIGATIONS, INSPECTIONS AND INQUIRIES UNDER THE CONSUMER PRODUCT SAFETY ACT

Subpart A—Procedures for Investigations, Inspections, and Inquiries

Sec.
1118.1 Definitions, initiation of investigations, inspections, and inquiries and delegations.
1118.2 Conduct and scope of inspections.
1118.3 Compulsory processes and service.
1118.4 Subpoenas.
1118.5 Investigational hearings.
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1118.7 Rights of witnesses at investigational hearings and of deponents at depositions.
1118.8 General or special orders seeking information.
1118.9 Motions to limit or quash subpoenas and general or special orders and delegation to modify terms for compliance.
1118.10 Remedies for failure to permit authorized investigations.
1118.11 Nonexclusive delegation of power.

Subpart B—Consent Order Agreements

1118.20 Procedures for consent order agreements.

AUTHORITY: Sec. 16, Pub. L. 92–573, 86 Stat. 1222 (15 U.S.C. 2065); sec. 19, Pub. L. 92–573, 86 Stat. 1224 (15 U.S.C. 2068); sec. 27, Pub. L. 92–573, 86 Stat. 1227 (15 U.S.C. 2076); as amended by Pub. L. 94–284, 90 Stat. 509.

SOURCE: 44 FR 34929, June 18, 1979, unless otherwise noted.

Subpart A—Procedures for Investigations, Inspections, and Inquiries

§ 1118.1 Definitions, initiation of investigations, inspections, and inquiries and delegations.

(a) *Definitions.* For the purpose of these rules, the following definitions apply:

(1) *Act* means the Consumer Product Safety Act (15 U.S.C. 2051, et seq.).

(2) *Commission* means the Consumer Product Safety Commission.

(3) *Firm* means a manufacturer, private labeler, distributor, or retailer of a consumer product, except as otherwise provided by section 16(b) of the Act.

(4) *Investigation* is an undertaking by the Commission to obtain information